

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

-----X  
RITE AID CORPORATION,

Plaintiff,

-against-

PURDUE PHARMA, L.P., THE PURDUE  
FREDERICK COMPANY, PURDUE  
PHARMACEUTICALS, L.P., P.F.  
LABORATORIES INC., THE PURDUE PHARMA  
COMPANY, and EUROCELTIQUE, SA,

Defendants.  
-----X

06 Civ. 15304 (SHS)

OPINION & ORDER

SIDNEY H. STEIN, U.S. District Judge.

Rite Aid Corporation brings this declaratory judgment action against Purdue Pharma, L.P., the Purdue Frederick Company, Purdue Pharmaceuticals, L.P., P.F. Laboratories Inc., the Purdue Pharma Company, and Euroceltique, SA (collectively “Purdue”) pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202. Rite Aid seeks a declaration that Purdue’s patents protecting a controlled-release oxycodone pain reliever sold under the brand name OxyContin are invalid and unenforceable. Purdue has moved to dismiss Rite Aid’s complaint pursuant to Fed. R. Civ. P. 12(b)(1) for lack of subject matter jurisdiction or, in the alternative, for a stay of these proceedings pursuant to this Court’s inherent powers.

The Court concludes that it lacks subject matter jurisdiction over the patent-infringement issues raised in this action because they do not present a “case of actual controversy” pursuant to 28 U.S.C. § 2201(a). In addition, to the extent that Rite Aid presses antitrust claims in this suit, the Court declines jurisdiction over those claims in

light of Rite Aid's separate pending suit against Purdue for antitrust violations.

Accordingly, the Court grants Purdue's motion to dismiss Rite Aid's complaint without prejudice.

## **I. BACKGROUND**

Rite Aid is in the business of selling pharmaceuticals directly to the public through its chain of thousands of pharmacies. Among the products sold by Rite Aid are OxyContin – Purdue's patented controlled-release oxycodone pain reliever – and its generic equivalents manufactured at various times by Endo Pharmaceuticals, Inc., Teva Pharmaceuticals, Inc., and Impax Laboratories, Inc. (Vucurevich Decl. ¶¶ 5, 12-13.) Beginning in 1999, Purdue filed patent-infringement actions against Endo, Teva, Impax, and Boehringer Ingelheim, GmbH<sup>1</sup> for marketing or attempting to market products that allegedly infringed Purdue's OxyContin patents. The action against Endo proceeded to trial, and on January 5, 2004, this Court held that Endo had infringed Purdue's OxyContin patents, but those patents were invalid due to Purdue's inequitable conduct in prosecuting them before the Patent and Trademark Office. See Purdue Pharma L.P. v. Endo Pharms., Inc., No. 00 Civ. 8029, 01 Civ. 2109, 01 Civ. 8177, 2004 U.S. Dist. LEXIS, at \*10 (S.D.N.Y. Jan. 5, 2004). The Court's ruling was initially affirmed by the U.S. Court of Appeals for the Federal Circuit in an opinion issued on June 7, 2005. See Purdue Pharma L.P. v. Endo Pharms. Inc., 410 F.3d 690 (Fed. Cir. 2005).

Nearly eight months later – on February 1, 2006 – the Federal Circuit withdrew its affirmance of this Court's January 5, 2004 Opinion and vacated the finding of patent invalidity. Purdue Pharma L.P. v. Endo Pharms., Inc., 438 F.3d 1123 (Fed. Cir. 2006).

---

<sup>1</sup> Boehringer has filed a New Drug Application with the Food and Drug Administration, but has never manufactured generic OxyContin.

Thereafter, Purdue sent a letter dated May 15, 2006 to Robert Sari, Esq. – the General Counsel and Secretary of Rite Aid – notifying him of the Federal Circuit’s decision. (Inz Decl., Exh. 1; Mem. Opp. Mot. Dismiss, Exh. 6.) In that letter, Purdue cautioned Rite Aid that the Federal Circuit’s ruling – a copy of which was attached to the letter – “may be important for you in considering your continued sale of infringing generic versions of OxyContin.” (Id.) Purdue then expressed its intention to “vigorously pursue its previously filed patent infringement actions” against the generic drug manufacturers, and “[i]n addition to the named defendants in these actions, Purdue intends, to the extent necessary, to pursue infringement claims against other entities that have been, or continue to be, involved in the manufacture, sale, distribution or importation of infringing generic OxyContin Tablets.” (Id.) The letter closed by encouraging Rite Aid to discuss its “involvement in the sale of infringing generic OxyContin Tablets . . . with your patent counsel.” (Id.)

In a subsequent letter addressed to Sari dated September 5, 2006, Purdue reiterated its concern that Rite Aid was selling “infringing generic versions of OxyContin manufactured by Impax Laboratories Inc.” (Inz Decl., Exh. 2.) Purdue stated its plans to “vigorously pursue its previously filed patent infringement action against Impax” and that it “reserves the right to pursue infringement claims against other persons that have been, or continue to be, responsible for the manufacture, sale, importation or distribution of infringing generic OxyContin products.” (Id.)

In October 2006, Purdue settled its infringement actions against Endo and Teva. (See Inz Decl., Exhs. 14, 16.) The settlements included licensing agreements permitting Endo and Teva to manufacture generic OxyContin and releases of patent-infringement

liability for both Endo and Teva and for third-party re-sellers – such as Rite Aid – for their past manufacture and sale of generic OxyContin. (See id., Rebuck Decl., Exh. A.)

Two months later, Rite Aid brought this declaratory judgment action arising from its sales of generic OxyContin products, which had not been authorized by Purdue, and what it perceived to be Purdue's threat of a patent-infringement suit. Rite Aid seeks a declaration that Purdue's OxyContin patents are invalid and therefore unenforceable, and Purdue has moved to dismiss the action for lack of subject matter jurisdiction.

Since the filing of Rite Aid's complaint and Purdue's motion to dismiss, Purdue has reached a settlement of its infringement action against Impax. As part of that settlement, Purdue released re-sellers of Impax's oxycodone product – including Rite Aid – from liability for past infringement (Rebuck Decl., Exh. B at P842924 – 842927), as it had done previously in connection with the Endo and Teva settlements (Inz Decl., Exh. 14, 16; Rebuck Decl., Exh. A). In addition, Purdue and Impax arrived at a licensing agreement for future sales by Impax of its generic OxyContin. (See Rebuck Decl., Exh. B.) As a result of this agreement, there is no unauthorized generic OxyContin on the market at present, because all three of the generic manufacturers have now reached settlement and licensing agreements with Purdue.

## II. DISCUSSION

### A. The Court Lacks Subject Matter Jurisdiction over the Patent-Infringement Issues Raised in this Action.

Purdue has moved to dismiss the patent-infringement issues raised in this action on the grounds that they do not constitute a “case of actual controversy” as required by the Declaratory Judgment Act, 28 U.S.C. § 2201(a).<sup>2</sup>

#### 1. *The Legal Standard Governing a Motion to Dismiss for Lack of Subject Matter Jurisdiction.*

A motion to dismiss for lack of subject matter jurisdiction made pursuant to Fed. R. Civ. P. 12(b)(1) will be granted “when the district court lacks the statutory or constitutional power to adjudicate” the action. Luckett v. Bure, 290 F.3d 493, 496 (2d Cir. 2002) (quoting Makarova v. United States, 201 F.3d 110, 113 (2d Cir. 2000)). When jurisdiction is evaluated, “the plaintiff asserting subject matter jurisdiction has the burden of proving by a preponderance of the evidence that it exists” and “the district court can refer to evidence outside the pleadings” to determine whether it has subject matter jurisdiction over the action. Id. at 496-97.

#### 2. *Purdue’s Motion to Dismiss Relies on a Discarded Test.*

Purdue contends that Rite Aid’s complaint fails to satisfy the two-part test established by the U.S. Court of Appeals for the Federal Circuit to determine whether a plaintiff can maintain a declaratory judgment action against a patentee. Under that standard, “[t]here must be both (1) an explicit threat or other action by the patentee which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it

---

<sup>2</sup> The Declaratory Judgment Act provides, in relevant part, that “[i]n a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.” 28 U.S.C. § 2201(a).

will face an infringement suit; and (2) present activity by the declaratory judgment plaintiff which could constitute infringement, or concrete steps taken with the intent to conduct such activity.” Teva Pharms. USA, Inc. v. Pfizer Inc., 395 F.3d 1324, 1332 (Fed. Cir. 2005). Purdue posits that its letters neither constituted a threat to sue nor created a “reasonable apprehension” that an infringement suit against Rite Aid was imminent. Primarily on that basis, Purdue requests that this action be dismissed.

Purdue’s reliance on this two-part test is misplaced because of recent U.S. Supreme Court and Federal Circuit decisions rejecting that standard. In January 2007, the U.S. Supreme Court questioned the validity of the “reasonable apprehension of suit” requirement contained in the first part of the test and observed that it “conflicts” with earlier Supreme Court precedent. MedImmune, Inc. v. Genentech, Inc., 549 U.S. \_\_\_, 127 S. Ct. 764, 774 n.11, 166 L. Ed. 2d 604 (2007). Shortly thereafter, the Federal Circuit issued two decisions<sup>3</sup> – SanDisk Corp. v. STMicroelectronics, Inc., 480 F.3d 1372 (Fed. Cir. 2007), and Teva Pharms. USA, Inc. v. Novartis Pharms. Corp., 482 F.3d 1330 (Fed. Cir. 2007) – that significantly altered the standard for determining whether subject matter jurisdiction exists in a declaratory judgment action testing a patent’s validity.

In SanDisk, the Federal Circuit noted the Supreme Court’s recent “rejection of [the] reasonable apprehension of suit test,” 480 F.3d at 1380, and concluded, in light of the Supreme Court’s MedImmune decision, that “Article III jurisdiction may be met where the patentee takes a position that puts the declaratory judgment plaintiff in the position of either pursuing arguably illegal behavior or abandoning that which he claims a right to do,” id. at 1381.

---

<sup>3</sup> Purdue’s motion to dismiss was filed prior to the issuance of these decisions.

Similarly, in Novartis, the Federal Circuit observed that an “‘actual controversy’ [in the context of the Declaratory Judgment Act] requires only that a dispute be ‘definite and concrete, touching the legal relations of parties having adverse legal interests; and that it be real and substantial and admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical set of facts.’” 482 F.3d at 1339 (quoting MedImmune, 127 S. Ct. at 771).

While the Federal Circuit has not yet defined the “outer boundaries of declaratory judgment jurisdiction” in the wake of the MedImmune decision, SanDisk, 480 F.3d at 1381, it has provided guidance on the issue. In particular, the court has held that

where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license, an Article III case or controversy will arise and the party need not risk a suit for infringement by engaging in the identified activity before seeking a declaration of its legal rights.

Id. This Court will apply these principles to the case at hand.

3. *Pursuant to SanDisk and Novartis, the Court Lacks Subject Matter Jurisdiction over the Patent-Infringement Issues Raised in this Action Because They Do Not Present a Case of “Actual Controversy.”*

Because the settlements in Endo, Teva, and Impax have removed all unauthorized generic OxyContin from the market and released third-party re-sellers from patent-infringement liability, there is no “actual controversy” over infringement of the OxyContin patents between Rite Aid and Purdue at this time.

In the absence of these settlements, Rite Aid’s declaratory judgment action would appear to fall within the parameters of SanDisk and Novartis. Here, Purdue – the

patentee – asserted patent rights based on Rite Aid’s sale of generic pharmaceuticals that allegedly infringed Purdue’s OxyContin patents. In the letters described above, Purdue put Rite Aid on clear and specific notice of the alleged patent infringement and expressed its plans to enforce its patent rights against those who manufacture, sell, distribute, or import infringing product “to the extent necessary.” (See Inz Decl., Exh. 1; Mem. Opp. Mot. Dismiss, Exh. 6.)<sup>4</sup> Rite Aid was, of course, a reseller of unlicensed generic OxyContin products at that time and maintained that it had the right to sell unlicensed generic OxyContin because of the alleged invalidity and unenforceability of Purdue’s OxyContin patents. Thus, assuming the existence of unauthorized generic OxyContin and taking the particulars of Purdue’s letters to the general counsel of Rite Aid into account, Purdue and Rite Aid would in all likelihood have had a definite and concrete dispute that fell within the Court’s declaratory judgment jurisdiction as articulated in SanDisk.

Specifically, if Rite Aid were unable to bring a declaratory judgment action to determine whether the OxyContin patents are in fact valid, it would be forced to either cease its sales of generic OxyContin or continue to sell the allegedly infringing drugs – all the while accruing potential liability to Purdue – and then face a suit for damages at a future time of Purdue’s choosing. This is precisely the type of choice that the Declaratory Judgment Act permits litigants to avoid. See MedImmune, 549 U.S. \_\_\_, 127 S. Ct. at 775 (“The rule that a plaintiff must destroy a large building, bet the farm, or . . .

---

<sup>4</sup> Purdue characterizes these letters as merely a means of “[n]otifying potential infringers of liability for damages.” (Mem. Supp. Mot. Dismiss at 15.) While this characterization of the letters may have been significant under the “reasonable apprehension” standard, it is no longer relevant. Under SanDisk, a patentee who “asserts rights under a patent based on certain identified ongoing or planned activity of another party” – as Purdue did in its letters to Rite Aid – may find itself subject to a declaratory judgment action. SanDisk, 480 F.3d at 1381.



risk treble damages and the loss of 80 percent of its business, before seeking a declaration of its actively contested legal rights finds no support in Article III.”).

However, Rite Aid no longer faces this choice. The settlement agreements between Purdue and each of the generic manufacturers – Endo, Teva, and Impax – have eliminated all unauthorized generic OxyContin from the market. Because there is currently no infringing product available for it to sell – and none on the horizon in the record of this action – Rite Aid does not face a choice between (a) not selling the generic OxyContin in order to avoid a threatened patent-infringement suit, on the one hand, and (b) selling the generic OxyContin but risking potential damages in a patent-infringement suit, on the other. Accordingly, Rite Aid is no longer confronted with the prospect of engaging in an “identified activity” that would cause it to “risk a suit for infringement,” SanDisk, 480 F.3d at 1381, and is therefore no longer in need of a declaratory judgment on patent infringement from this Court.

Rite Aid maintains that a live controversy exists between it and Purdue because the Endo, Teva, and Impax releases do not unequivocally bar Purdue from bringing a patent-infringement action against Rite Aid for its prior sales of unauthorized generic OxyContin. Observing that the Impax settlement includes a “blow-up” clause that nullifies the release upon a “final non-appealable judgment” invalidating certain provisions of the settlement agreement, releases, or licensing agreement (Rebuck Decl., Exh. B at P842918), Rite Aid posits that it may face a patent-infringement suit if the “blow-up” clause is triggered in the future.

Rite Aid does not contend, however, that any of the provisions that trigger the “blow-up” clause face imminent invalidation in a final non-appealable judgment or even

that they are currently the subject of litigation. Thus, the likelihood that the “blow-up” clause will be triggered is, at most, remote at this time, and Rite Aid cannot rely on the mere possibility that the Impax release might be nullified at some point in the future – thereby exposing Rite Aid to a possible patent-infringement suit – to satisfy the “actual controversy” requirement of the Declaratory Judgment Act. A declaration entered by this Court on such a contingent basis would constitute an “opinion advising what the law would be upon a hypothetical set of facts” rather than a resolution of a dispute that is both “definite and concrete” and “real and substantial.” MedImmune, 549 U.S. \_\_\_, 127 S. Ct. at 771.

Accordingly, on the facts as they exist today, there is no patent-infringement dispute between Rite Aid and Purdue that would “admit of specific relief through a decree of” this Court, id., and therefore the Court lacks subject matter jurisdiction over the patent-infringement issues raised in this action.

B. Rite Aid’s Antitrust Injuries Are Already before the Court in Another Suit and Will Not Be Entertained in this Declaratory Judgment Action As Well.

Anticipating that the Court may conclude that it does not currently face the risk of patent-infringement liability to Purdue, Rite Aid contends that it has suffered an economic “injury in fact” that independently establishes subject matter jurisdiction under the Declaratory Judgment Act. Rite Aid maintains that it has been injured by Purdue’s settlement agreements with Endo, Teva, and Impax because those agreements eliminated unauthorized generic OxyContin from the market and thereby prevented Purdue from purchasing and reselling that product. Under Rite Aid’s theory, Purdue’s enforcement of its patent rights has caused Rite Aid an actual injury – lost profits on unauthorized generic OxyContin sales – that can be remedied by a declaration from this Court

invalidating Purdue's patents because unlicensed manufacturers would then produce – and Purdue, in turn, would purchase and resell – generic OxyContin.

Because Rite Aid claims to have been harmed by settlement agreements that allegedly restrain trade in generic OxyContin, its injury sounds in antitrust law. However, Rite Aid's antitrust claims against Purdue for enforcing the OxyContin patents are currently before this court as part of the multidistrict OxyContin litigation in another suit – CVS Pharmacy, Inc. and Rite Aid Corporation v. Purdue Pharma, L.P., The Purdue Frederick Company, P.F. Laboratories Inc., The Purdue Pharma Company, No. 04 Civ. 3719 – which has been temporarily stayed, pending the determination of patent validity in proceedings on remand from the Federal Circuit. See Multidistrict Litigation Order No. 2 dated Mar. 30, 2006. Rite Aid cannot use this declaratory judgment action as a procedural device to evade the Court's order staying the antitrust suit.

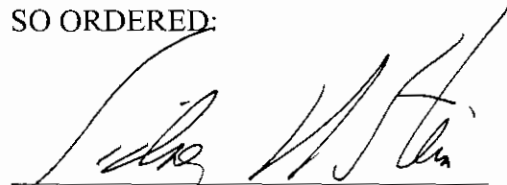
In light of the existence of Rite Aid's pending antitrust action – and taking into account all of the circumstances presented by the OxyContin multidistrict litigation as a whole – the Court, pursuant to its “broad grant of discretion” under the Declaratory Judgment Act, Dow Jones & Co. v. Harrods Ltd., 346 F.3d 357, 359 (2d Cir. 2003) (citing 28 U.S.C. § 2201(a)), declines to exercise jurisdiction over Rite Aid's antitrust claims in this declaratory judgment action. See id. at 359-60 (factors for courts to consider when exercising discretion pursuant to the Declaratory Judgment Act include “whether the proposed remedy is being used merely for ‘procedural fencing’” and “whether there is a better or more effective remedy”).

### III. CONCLUSION

Because the patent-infringement issues raised in this action do not present a “case of actual controversy” as required by the Declaratory Judgment Act, this Court lacks subject matter jurisdiction over those issues. To the extent that Rite Aid presses antitrust claims in this suit, the Court exercises its discretion to decline jurisdiction over those claims in light of Rite Aid’s pending antitrust suit against Purdue. Therefore, Purdue’s motion to dismiss Rite Aid’s complaint without prejudice is granted.

Dated: New York, New York  
August 21, 2007

SO ORDERED:

  
\_\_\_\_\_  
Sidney H. Stein, U.S.D.J.